operation of a federal savings bank, pursuant to § 225.25(b)(9) of the Board's Regulation Y. The proposed activity will be conducted throughout the State of Georgia.

Board of Governors of the Federal Reserve System, January 30, 1995.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 95–2676 Filed 2–2–95; 8:45 am]

BILLING CODE 6210–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 95G–0009]

American Dairy Products Institute; Filing of Petition for Affirmation of GRAS Status

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the American Dairy Products Institute has filed a petition (GRASP 1G0371), proposing to affirm that whey protein isolate and dairy product solids are generally recognized as safe (GRAS) as direct human food ingredients and to broaden the specifications for reduced lactose whey, reduced minerals whey, and whey protein concentrate.

DATES: Written comments by April 4, 1995.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Rudolph Harris, Center for Food Safety and Applied Nutrition (HFS–207), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3090.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (secs. 201(s) and 409(b)(5) (21 U.S.C. 321(s) and 348(b)(5)) and the regulations for affirmation of GRAS status in § 170.35 (21 CFR 170.35), notice is given that the American Dairy Products Institute, 130 North Franklin St., Chicago, IL., (c/o Keller and Heckman, Washington, DC) has filed a petition (GRASP 1G0371), proposing that whey protein isolate and dairy product solids be affirmed as GRAS for use as direct human food ingredients, and to broaden the specifications for reduced lactose whey, reduced minerals whey, and whey protein concentrate.

The petition has been placed on display at the Dockets Management Branch (address above).

Any petition that meets the requirements outlined in §§ 170.30 (21 CFR 170.30) and 170.35 is filed by the agency. There is no prefiling review of the adequacy of data to support a GRAS conclusion. Thus, the filing of a petition for GRAS affirmation should not be interpreted as a preliminary indication of suitability for GRAS affirmation.

The potential environmental impact of this action is being reviewed. If the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c).

Interested persons may, on or before April 4, 1995, review the petition and file comments with the Dockets Management Branch (address above). Two copies of any comments should be filed and should be identified with the docket number found in brackets in the heading of this document. Comments should include any available information that would be helpful in determining whether the substance is, or is not, GRAS for the proposed use. In addition, consistent with the regulations promulgated under the National Environmental Policy Act (40 CFR 1501.4(b)), the agency encourages public participation by review of and comment on the environmental assessment submitted with the petition that is the subject of this notice. A copy of the petition (including the environmental assessment) and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 26, 1995.

Alan M. Rulis,

Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 95–2629 Filed 2–2–95; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95D–0004]

Vaginal Contraceptive Drug Products; Guidance on Content of New Drug Applications; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document for manufacturers of vaginal contraceptive drug products entitled, ''Guidance for Development of Vaginal Contraceptive Drugs.'' This guidance document is intended to facilitate the development of data in support of new drug applications (NDA's), which FDA has proposed to require for all over-the-counter (OTC) vaginal contraceptives.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''Guidance for Development of Vaginal Contraceptive Drugs'' to the Division of Metabolism and Endocrine Drug Products (HFD–510), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Requests should be identified with the docket number found in brackets in the heading of this document. Send two self-addressed adhesive labels to assist that office in processing your requests. The guidance document is available for public examination in the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Lisa Stockbridge, Center for Drug Evaluation and Research (HFD–510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–3520.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a guidance document entitled ''Guidance for Development of Vaginal Contraceptive Drugs'' on content of NDA's for manufacturers of vaginal contraceptive drug products. As part of FDA's ongoing review of OTC drug products, the agency is publishing elsewhere in this issue of the **Federal Register** a proposed rule that addresses OTC vaginal contraceptive drug products. The preamble to that proposed rule sets forth FDA's determination that the effectiveness of OTC vaginal contraceptives is highly variable and is dependent on final formulation. Because in vitro testing does not adequately predict the effectiveness of these products, FDA is proposing to call for the submission of product-specific marketing applications for vaginal contraceptives, including effectiveness data obtained from clinical studies of the products in their final formulations.

The guidance document is intended to assist manufacturers in the preparation of NDA's for vaginal contraceptive drug products. It describes the chemistry, pharmacology,